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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Dallas District
3310 Live Oak Street
Dallas, Texas 75204-6191

June 2, 1997

Ref: 97-DAL-WL-24

WARNING LETTER

VIA FACSIMILE AND FEDERAL EXPRESS

Ms. Jeri C. Tiller, Owner
Tiller Mind and Body, Inc.
2204 N.W. Loop 410 #2C
San Antonio, Texas 78230

Dear Ms. Tiller:

During an inspection of your firm located in San Antonio, Texas, on March 4 through 7, 1997, a Texas Department of Health investigator, under contract to the Food and Drug Administration, determined that your firm manufactures colonic irrigation system devices as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

Our records indicate that your firm submitted a premarket notification 510(k), K941279, for the LIBBE colonic irrigation device on March 13, 1994. On October 12, 1995, the LIBBE colonic irrigation device was found substantially equivalent (SE) to similar devices classified under Title 21 of the Code of Federal Regulations (21 CFR) Part 876.5220 as colonic irrigation systems. Colonic irrigation systems are devices intended to cleanse the lower colon when medically indicated, such as before radiological or endoscopic examinations. Some time after receiving an SE determination your firm modified the intended use of the device through labeling materials entitled ""LIBBE" COLON HYDROTHERAPY EQUIPMENT * TRAINING * SUPPLIES." The new intended uses include the treatment of "low-grade chronic infections", "improvement of both capillary and lymphatic circulation, and of liver function." and "acne, allergies, asthma" These intended uses require an application for premarket approval (PMA), however, an application has not been submitted to the FDA. Failure to submit a notice or other information respecting a change in the intended use of a device, as required by 807.81(a)(3)(i), results in the device being misbranded within the meaning of Section 502(o) of the Act.

The LIBBE colonic irrigation device is also adulterated within the meaning of Section 501(f)(1)(B) of the Act, in that it is a class III device under Section 513(f) of the Act and does not have an approved PMA, and it is not exempt from such requirements under an investigational device exemption (IDE) Section 520(g).

Additionally, the LIBBE colonic irrigation device is misbranded within the meaning of Section 502(a) of the Act, in that references to the FDA in labeling materials entitled "'LIBBE" COLON HYDROTHERAPY EQUIPMENT * TRAINING * SUPPLIES" is prohibited. Specific statements include: "Manufactured in Compliance with All FDA Guidelines, Patent Pending" and "Trade Your Non-FDA, Old Equipment Towards Purchase/Lease of a "LIBBE"".

The TDH investigator also documented serious deviations from the Good Manufacturing Practice (GMP) for Medical Device Regulations (21 CFR Part 820). These deficiencies cause the LIBBE colonic irrigation devices to be adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for their manufacturing, packing, storage or installations are not in conformance with GMP. The inspectional observations, FDA-483, were discussed with you at the completion of the inspection. GMP deficiencies noted during the inspection include:

Failure of the device master record to include device specifications, production process specifications, quality assurance procedures and specifications, packaging and labeling specifications, and to include the authorization of any changes by the signature of a designated individual(s), as required by 21 CFR 820.181.

Failure to maintain device history records including the dates of manufacture, quantity manufactured, and quantity released for distribution, as required by 21 CFR 820.184.

Failure to review, evaluate, and maintain by a designated individual(s) all records of written and oral complaints relative to the identity, quality, reliability, safety, effectiveness, or performance of a device, as required by 21 CFR 820.198(a). For example, service calls involving the possible failure of a device to meet any of its performance specifications were not reviewed, evaluated, and maintained.

Failure to establish written procedures for finished device inspections to assure that device specifications are met, as required by 21 CFR 820.160.

Failure to have in place an adequate organizational structure to assure that the devices produced are manufactured in accordance with the requirements of the GMP regulation, as required by 21 CFR 820.20.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all warning letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no pending applications for premarket approval (PMA's) or export approval requests will be approved and no premarket notifications (Section 510(k)'s) will be found to be substantially equivalent for products manufactured at your San Antonio, Texas facility until the GMP violations have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction and/or civil penalties.

Please notify this office in writing within fifteen (15) working days of the receipt of this letter, of the specific steps you have taken to correct these violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the correction will be completed. We will be glad to meet with you and discuss these violations if you do not understand this letter.

Your response to this letter should be addressed to James Austin Templer, Compliance Officer, at the above letterhead address.

Sincerely yours,

Joseph R. Baca
District Director